IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re the Application of:	Group Art Unit: 1617
THOR	Examiner: Yong Soo Chong
Serial No.: 10/049,427	Confirmation No.: 1087
Filed: May 6, 2002	APPELLANT'S APPEAL BRIEF PURSUANT TO 37 C.F.R. § 41.37
Atty. File No.: 4220-78-PUS	
For: "Methods of Using Rapid-Onset Selective Serotonin Reuptake Inhibitors for Treating Sexual Dysfunction"	Filing Electronically

Board of Patent Appeals and Interferences
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313

Appellant submits this Brief in furtherance of the Notice of Appeal filed on January 3, 2007. The fee of $500.00 set forth in 37 C.F.R. §41.20 (b)(2) for filing a Brief in support of an appeal is being authorized in connection with this filing. Please charge any underpayment or credit any overpayment to Deposit Account No. 19-1970.

(i) Real Party in Interest. The real party in interest is APBI Holdings, LLC, which is a subsidiary of Pharmaceutical Product Development, Inc.

(ii) Related Appeals and Interferences. There are no related appeals or interferences.

(iii) Status of Claims. Claims 1-36, 43-50 and 55 are canceled. Claims 37-42 and 51-54 are rejected and are on appeal.

(iv) Status of Amendments. There are no unentered amendments.

(v) Summary of Claimed Subject Matter.

The currently pending claims, recited in the Claims Appendix hereto, are directed to methods of treating or managing the sexual dysfunction of premature ejaculation in a male mammal by the administration of dapoxetine to the mammal (see, Specification at page 1, lines 5-10 and page 10, lines 4-10).

Premature ejaculation is a common sexual dysfunction and refers to persistent or recurrent ejaculation with minimal sexual stimulation before, upon or shortly after penetration, and before the person wishes it (page 1, lines 26-29).

Dapoxetine is a rapid onset selective seretonin reuptake inhibitor (page 7, lines 9-18 and page 10, lines 13-21). Dapoxetine may be present in two isomers and may be formulated as a number of pharmaceutically-acceptable salts (page 10, lines 15-20; page 12, lines 4-21 and page 14, line 11- page 15, line 13). Dapoxetine is administered in a dose that is therapeutically effective to treat or manage premature ejaculation (page 10, lines 4-8; page 19, lines 26-30 and page 20, line 25 – to page 26, line 5).

Advantageously, dapoxetine may be administered on an as-needed basis or in a dose and at a time sufficiently prior to the anticipated therapeutic effect, without the need for chronic administration or overdosing of the drug (page 6, lines 12-20 and page 19, lines 20-25). This dose is preferably between about 0.01mg and about 200mg (page 21, line 1) and the time sufficient for administration is preferably a time period between immediately prior to, and 12 hours prior to, sexual activity (page 20, lines 13-15). More preferably, this time period for effective as-needed administration of dapoxetine may range between a time immediately prior to sexual activity and 10 hours prior to sexual activity or 8 hours prior to sexual activity or even 4 hours prior to sexual activity (page 20, lines 15-19). In preferred embodiments of the present invention, the as-needed administration of a therapeutically effective amount of dapoxetine is timed between immediately prior to, and 3 hours prior to,

anticipated sexual activity (see original claim 52) or between 30 minutes prior to, and 3 hours prior to, sexual activity (see original claim 53).

Another substantial advantage of the currently claimed treatment is the effectiveness of dapoxetine to treat or manage premature ejaculation in the absence of a priming dose (page 5, line 23-age 6, line 10). That is, dapoxetine is effective following a single dosage, including the very first dosage, thereby eliminating the requirement for initial or "priming doses" to establish a therapeutic level of the drug in anticipation of sexual activity (page 8, lines 19-23). This avoids the adverse effects or lack of efficacy expected following multiple or chronic administration of drugs that have previously been tested for the treatment of premature ejaculation (page 4, line 23- page 5, line 22).

(vi) Grounds of Rejection to be Reviewed on Appeal.

The sole ground of rejection on appeal is whether Claims 37-42 and 51-54 are unpatentable under 35 U.S.C. §103(a) over McMahon et al. (J. Urology, 161:1826-30, 1999) and Lane (J. Psychopharmacology, 11(1):72-82, 1997) in view of Eli Lilly (ZA 9300694) and Robertson et al. (U.S. Patent No. 5,135,947).

Specifically, the Examiner characterizes McMahon et al. as teaching the treatment of premature ejaculation (PE) with the SSRI paroxetine hydrochloride "administered on an as-needed basis without a priming dose 3-4 hours prior to planned intercourse," citing the title and abstract. The Examiner also cites Lane as teaching low dosages of SSRI's administered on an as-needed basis for treatment of PE. Eli Lilly is cited as teaching the treatment of PE with fluoxetine, dapoxetine and duloxetine, and Robertson is cited as teaching the instantly claimed compounds as SSRI's.

(vii) Argument.

Summary

Contention 1 The combination of references cited by the Examiner fails to teach or suggest all of the claim limitations, and in particular, the limitation that administration on an as-needed basis is effective in the absence of priming doses. The Examiner mischaracterizes McMahon et al. as teaching administration of paroxetine "on an as needed basis without a priming dose 3-4 hours prior to planned intercourse." (10/3/06 Off. Action, p.

3, 11. 3-6) In fact, McMahon et al. do not disclose administration of paroxetine in the absence of priming doses and do not provide sufficient information to determine whether or not the as-needed administration in McMahon et al. was conducted in the absence of priming doses. The Examiner attempts to equate McMahon et al.'s statement that ***as-needed dosing*** of paroxetine is successful with the unfounded conclusion that ***as-needed dosing in the absence of priming doses*** is successful. Additionally, the Examiner incorrectly construes the initial as-needed dosing data (the "week 1 data") of McMahon et al. as showing ***as-needed dosing in the absence of priming doses,*** when those data cannot appropriately be considered to have statistical significance. The Examiner does not even characterize Lane as disclosing as-needed dosing that is effective in the absence of priming doses. Neither of the secondary references disclose the element of as-needed dosing of an SSRI being effective to treat PE in the absence of priming doses. Accordingly, the Examiner has not established *a prima facie* case of obviousness because none of the references discloses as-needed dosing in the absence of priming doses.

Contention 2 The rejection under 35 U.S.C. § 103(a) McMahon, Lane, Lilly and Robertson is based on an impermissible "obvious to try" standard. None of the prior art showed any compounds for treatment of PE that were effective with as-needed administration in the absence of priming doses. Because SSRI's were known to affect sexual function, multiple compounds were being considered in the prior art for treatment of PE. However, the skilled person would not have had a reasonable expectation of success for the use of dapoxetine to effectively treat PE on an as-needed basis in the absence of priming doses without the benefit of hindsight using the Applicant's disclosure as a blueprint.

Contention 3 With regard to Claims 41, 42 and 52-54, administration of dapoxetine immediately prior to, to about 3 hours prior to a sexual activity is not mere optimization because efficacy of that dosing regimen is unexpected and the prior art teaches away from the use of this dosing regimen. None of the cited prior art discloses administration within 3 hours prior to sexual activity. Administration of SSRI's for their primary indication of depression is typically daily, chronic dosing. The prior art considering the use of SSRI's for treating sexual dysfunction and in particular PE, had, prior to the present invention, not found on-demand therapy to be effective. Since the timing and frequency of sexual activity is not routine or predictable, effective as-needed treatment in the

absence of priming doses is a significant advantage of the present invention. Since such a therapy was not previously available, despite its advantages, the invention of Claims 41, 42, and 52-54 is unexpected and not merely routine optimization.

Rejection of Claims 37-42 and 51-54 under 35 U.S.C. §103(a)

Contention 1. The Examiner has not established *a prima facie* case of obviousness because none of the cited references, alone or in combination, disclose the claim element of effective treatment of premature ejaculation ***in the absence of priming doses.***

To establish *a prima facie* case of obviousness, an examiner must identify a motivation to combine reference teachings with a reasonable expectation of success in a combination that teaches or suggests all of the claim limitations. MPEP 2143.03. In the standing rejection, the combination of references does not teach or suggest the claim limitation that the administration of dapoxetine or a pharmaceutically acceptable salt thereof on an as-needed basis for the treatment of premature ejaculation is effective in the absence of priming doses.

Contention 1.1. The Examiner has mistakenly construed the "as-needed" use of paroxetine as described in McMahon et al. as demonstrating effectiveness to treat premature ejaculation "as-needed in the absence of priming doses."

McMahon et al. describe two studies evaluating the as-needed administration of paroxetine for treating PE. The first study begins with as-needed administration and the second study begins with three weeks of daily administration of paroxetine before starting as-needed administration. McMahon et al. conclude that ejaculatory control is better in the second study (with prior daily dosing) than in the first study (no prior daily dosing). Based on McMahon et al. finding some benefit for ejaculatory control in the first study without prior daily dosing, the Examiner concludes, improperly, that the first study demonstrates that as-needed dosing of paroxetine for treating PE is effective in the absence of priming doses.

The evidence in the record shows that a priming dose is a prior dose of a drug that has not been cleared from the body at the time of administration of a subsequent dose of the

drug. (Declaration of David A. Rivas, MD submitted on July 27, 2006, ¶ 5, reproduced in the Evidence Appendix hereto, section viii) McMahon et al.'s finding of some benefit for ejaculatory control in the first study was based on evaluating mean ejaculatory latency time in the study groups calculated using all data throughout the treatment phases (i.e., multiple instances of intercourse per week over 4 week treatment phases) when paroxetine had been used over a period of time (Rivas Decl., ¶ 4.c.), which cannot be considered "in the absence of a priming dose" (Rivas Decl., ¶ 4.d.). In fact, the "as-needed" use of paroxetine in McMahon et al. was not structured to avoid a priming dose effect; therefore, the study does not provide sufficient information for the skilled person to conclude that paroxetine is effective to treat premature ejaculation as-needed in the absence of priming doses. (Rivas Decl., ¶ 4.f.) Even though McMahon et al. do not refer to or discuss priming doses, the Examiner improperly equates McMahon et al.'s as-needed dosing without an initial three week period of daily treatment with the claimed language of as-needed dosing that is effective in the absence of priming doses.

Contention 1.2. The Examiner is mistakenly relying on the week 1 data in McMahon et al. as being statistically significant and as showing effective treatment of premature ejaculation in the absence of priming doses.

The initial as-needed dosing data from the first study in McMahon et al (e.g., as shown in Fig. 1, week 1, hereinafter, the "week 1 data") cannot be relied upon by one skilled in the art as demonstrating an increase in ejaculatory latency by paroxetine over control. The Examiner, however, characterizes McMahon et al. as "clearly illustrat[ing] (Figure 1) that the mean ejaculatory interval was seen to increase after one week of administration of paroxetine in both Groups A and B by identical amounts and that the increase was more than that observed for placebo." (10/3/06 Office Action, p. 6, 11. 18-21) The Examiner further commented that "McMahon et al. does not state that the results of week 1 are *not* statistically superior." (10/3/06 Office Action, p. 7, 11. 1-2) These statements of the Examiner, demonstrating reliance on the week 1 data in support of the rejection, are *contrary* to the understanding that one skilled in the art would have of the week 1 data.

McMahon et al. does not provide sufficient information to determine whether the

week 1 treatment data of Study 1 are statistically significantly different from the control data. (Rivas Decl., ¶ 3.b.) Further, contrary to the Examiner's position, the fact that McMahon et al. does not state that the week 1 treatment data of Study 1 are statistically significantly different from the control data conveys to one skilled in the art that the authors do not consider the results at week 1 to be statistically significant, and therefore, it would be inappropriate for one to conclude that the week 1 data in Study 1 are statistically significant. (Rivas Decl., ¶ 3.a.) Consequently, as one skilled in the art, Dr. Rivas would not rely on the week 1 data as demonstrating an increase in ejaculatory latency. (Rivas Decl., ¶ 3.c.)

In responding to the 3/10/05 Office action, Applicant requested that if the Examiner continued to rely on the week 1 data of McMahon et al., the Examiner provide documentary evidence that it is proper to rely on data that is not statistically significant (MPEP 2144.03) or provide an Examiner's affidavit pursuant to 37 CFR 1.104(d)(2) to that effect. In the 10/4/05 and 10/3/06 Office actions, the Examiner finds this requirement to be "not necessary" for two reasons. (see 10/3/06 Office Action, p. 6, 11. 3-18) The first (that a single dose of a drug would constitute a "priming dose" for the rest of time) reflects that the Examiner misunderstands the concept of a priming dose since a priming dose is simply a dose of a drug that has not been cleared from the body at the time of a subsequent dose. Thus, a single dose of a drug would constitute a priming dose if it is not cleared from the body at the time of a subsequent dose, but would not constitute a priming dose if it has been cleared. The second reason (the Examiner's position that while McMahon et al. suggests that a priming dose is preferred, it is not required) is simply a reiteration of the Examiner's position discussed in detail in Contention 1.1. As discussed above, the McMahon et al. study was not structured to avoid a priming dose effect and therefore, the skilled person cannot draw any conclusions about whether paroxetine is effective when administered as-needed in the absence of priming doses.

Contention 1.3. Even if the Examiner established *a prima facie* case of obviousness that McMahon et al. discloses "as-needed in the absence of priming doses," Applicant has successfully rebutted it with the Rivas Declaration.

As discussed above in Contentions 1.1 and 1.2, Applicant's position that the cited

combination of references does not disclose the claim element of effective treatment of premature ejaculation in the absence of priming doses is supported by the Rivas Declaration. In the Office action dated 10/3/06, the Examiner has provided no evidence or explanation to overcome the conclusion in the Rivas Declaration that McMahon et al. does not allow the skilled person to make any conclusion regarding the efficacy of as-needed paroxetine in the absence of priming doses because the Examiner improperly equates "as-needed" dosing with "as-needed" dosing that is effective "in the absence of priming doses." The Examiner has provided no evidence or explanation to overcome the conclusion in the Rivas Declaration that the week 1 data is not statistically significant and cannot be relied upon to demonstrate an increase in ejaculatory latency.

Contention 1.4. The Examiner does not even contend that Lane discloses the as-needed use of SSRI's to treat premature ejaculation being effective in the absence of priming doses.

None of the Office actions in this application have cited Lane as demonstrating the as-needed use of SSRI's to treat premature ejaculation being effective ***in the absence of priming doses.*** Rather, the Examiner has cited Lane (Lane, p. 79, col. 2, first full para.) as showing the as-needed administration of SSRI's for treating PE. Both the Waldinger et al. and the Mendels et al. studies referenced there are daily dosing studies and not "as-needed."

The only study referenced in Lane relevant to as-needed dosing is the Swartz abstract. Even reviewing the full text of the Swartz abstract, it cannot be determined whether a priming dose effect was being seen in the results due to a number of significant shortcomings of this abstract that the Examiner has not addressed. Swartz averages daily dosing and as-needed dosing results and therefore, no conclusion can be reached about the effects of as-needed dosing alone. The Swartz reference is ambiguous in regard to priming doses when stating "[a] positive response was present after the initial dose" because it is unclear whether a "positive response" was seen with the initial dose or was seen after the initial dose with second and subsequent doses. Further, no criteria are given for a "positive response," and the small number of patients involved with the variety of dosing regimens does not allow any statistical significance to be given to these results. Further, the statement in Swartz that the 26-hour elimination half life of sertraline allows considerable liberties in

dosing schedules has more significance in regard to the claimed invention than the Examiner admits. The Examiner states that this comment only means that "administration schedules may be adjusted to the particular needs of a patient." Because of this relatively long half life, a given dose of sertraline will remain in the body over at least 104 hours (four half-lives). This comment, therefore, suggests that sertraline does not need to be given on an as-needed basis since levels of the drug remain in the body for a long time. In addition, since the drug remains in the body for such a long time, a given dose can function as a priming dose for subsequent administrations of the drug.

Contention 2. The rejection under 35 U.S.C. § 103(a) McMahon, Lane, Lilly and Robertson is based on an impermissible "obvious to try" standard.

In making the rejection under 35 U.S.C. § 103(a), the Examiner concludes that it would be obvious to the skilled person to substitute dapoxetine or its pharmaceutically acceptable salts for the compounds of McMahon et al. or Lane to arrive at the claimed method (10/3/06 Office action, pp. 2-4) of treating PE by administering dapoxetine on an as-needed basis wherein the treatment is effective in the absence of priming doses. The Examiner has improperly applied an "obvious to try" standard in making this rejection.

The Federal Circuit has held that an "obvious to try" situation exists when a general disclosure may pique a scientist's curiosity, such that further investigation might be done as a result of a disclosure, but the disclosure itself does not contain a sufficient teaching of how to obtain the desired result, or that the claimed result would be obtained if certain directions were pursued. In re Eli Lilly & Co., 14 USPQ 2d 1741, 1743 (Fed.Cir. 1990). However, "obvious to try" is not to be equated with obviousness under 35 U.S.C. §103. See Gillette Co. v. S.C. Johnson & Son, Inc., 16 USPQ 2d 1923, 1928 (Fed.Cir. 1990).

In Gillette Co. v. S.C. Johnson & Son, Inc., the Court considered whether a post-foaming shaving gel composed of four known components was patentable. While the combination of claim components may have been "obvious to try" because the individual components were known in the art, the Court emphasized the need to look at the invention as a whole. In doing so, the Court upheld the District Court's finding of nonobviousness by focusing on the unique properties that resulted from the claimed invention, namely a post-foaming shaving gel having properties that were superior to any product on the market. In

the present case, it is also important to focus on the unique aspect of the claimed method, namely, that the method is effective for treating PE on an as-needed basis in the absence of priming doses. Although the Examiner mischaracterized McMahon et al. as showing effective as-needed treatment in the absence of priming doses, the present method is superior to any known method for treating PE because it is the only method effective in the absence of priming doses.

The claims at issue in another case that turned on the obviousness to try standard were very similar to the claims of the present case. In the present case, the claims are for the use of an SSRI, dapoxetine, to treat PE in the absence of priming doses. In Eli Lilly & Co. v. Teva Pharms. USA, Inc., 2004 U.S. Dist. LEXIS 14724 (S.D. Ind., July 29, 2004), the Court reviewed claims to the use of an SSRI, fluoxetine, to treat a condition other than depression, pre-menstrual syndrome ("PMS"). The Federal Circuit upheld the District Court's conclusion of claim validity based on a finding that, while in hindsight it might have been "obvious to try" fluoxetine to treat PMS, it was not obvious under 35 U.S.C. §103. Eli Lilly & Co. v. Teva Pharmaceuticals USA, Inc., *2005 U.S. App. LEXIS 14583* (Fed. Cir. 2005). In that case, prior to the invention, the etiology of PMS was not known. However, the prior art showed a correlation between PMS severity and decreased serotonin levels, and the prior art suggested the treatment of PMS with agents that influence the serotonergic pathway (tryptophan, chlorimipramine and trazodone hydrochloride). Fluoxetine was known to alleviate serotonin deficiencies. Given this background, the Court found that a "can't hurt to try" attitude may have existed in the mind of those of ordinary skill in the art, and that perhaps, in hindsight, it would have been "obvious to try" fluoxetine to treat PMS but these conditions were insufficient to establish obviousness under 35 U.S.C. §103. In making its decision, the Court also considered that the District Court's correct conclusion that an "obvious to try" situation was based on (1) other drugs (besides fluoxetine) being considered for treating PMS; and (2) studies with other therapies being unsuccessful.

The facts of Eli Lilly v. Teva parallel the facts of the present application. The etiology of PE is not known. Also, while SSRI's are known to affect sexual function and have been suggested for treatment of PE, no SSRI or any other compound has been found to be effective in the treatment of PE on an as-needed basis in the absence of priming doses. Further, as in Eli Lilly v. Teva, many potential compounds including fluvoxamine, paroxetine and sertraline, both as-needed and chronic administration, in addition to non-

SSRI compounds, were being considered to treat the indication in question. None, however, were successful for as-needed treatment in the absence of priming doses. Further, the skilled person could not expect success when testing the many different compounds for treatment of PE because at the time of filing and even years subsequent, the art recognized that effective as-needed treatment for PE was not available using any compound. The McMahon 2005 paper, discussed below, supports this conclusion.

In the Amendment submitted on July 8, 2005 in response to the Office action dated March 10, 2005, Applicant cited a 2005 paper by McMahon, the lead author of the McMahon et al. primary reference. (McMahon, C., J. Sex Med., Supp2:94-5 (2005)). Neither of the two most recent Office actions (October 4, 2005 and October 3, 2006) address this reference, yet the Examiner in the most recent Office action maintains that "[o]ne would have been motivated to substitute the SSRI's of McMahon et al. and Lane with the SSRI's as instantly claimed because of an expectation of success in treating premature ejaculation with an SSRI, as taught by both McMahon et al. and Lane." While the Examiner's position is that McMahon et al. creates an expectation of success in treating PE with any SSRI (and specifically, dapoxetine), the lead author of McMahon states in 2005 that "[e]ffective, on-demand therapy that is effective within the time frame most suitable for the PE patient . . . is not currently available." Contrary to MPEP 707.07(f), the Examiner has not addressed the substance of Applicant's argument on this point.

While a researcher may have had the attitude that it "can't hurt to try" any given serotonergic agent, the prior art does not contain a teaching sufficient to establish that the as-needed use of dapoxetine in the absence of priming doses would be effective and therefore, it would not have been obvious to one of skill in the art as required by 35 U.S.C. §103.

Rejection of Claims 41, 42 and 52-54 under 35 U.S.C. §103(a)

Contention 3. Administration of dapoxetine immediately prior to, to about 3 hours prior to a sexual activity is not mere optimization because efficacy of that dosing regimen is unexpected and the prior art teaches away from it.

The Examiner takes the position that the claimed administration times in Claims 41,

42 and 52-54 are obvious (10/3/06 Office Action, p.4, ll. 11-15), citing In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955): "[w]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." Claims 41, 42 and 52-54, all recite administration of dapoxetine or a pharmaceutically acceptable salt thereof within three hours prior to a sexual activity.

A *prima facie* case of obviousness based on ranges that touch at endpoints can be overcome by either unexpected properties in the claimed range or prior art teaching away from the claimed range. In re Malagari, 182 USPQ 549, 553 (CCPA 1974).

Even assuming that the Examiner has established *a prima facie* case of obviousness against Claims 41, 42, and 52-54, (which Appellant does not admit) such a case of *prima facie* obviousness is overcome by the prior art teaching away from administration of an SSRI for treatment of PE within the time frame of three hours or less prior to sexual activity. The McMahon et al. protocol was for administration of paroxetine "3 to 4 hours before planned intercourse." The only study referenced in the Lane article purporting to show the use of an SSRI on an as-needed basis was the Swartz abstract which does not disclose a detailed protocol for administration. Moreover, the administration of SSRI's for their primary indicated use of depression requires chronic daily dosing. Further, as indicated in the McMahon 2005 article, as recently as 2005, it was believed that on-demand therapy that is effective within the time frame suitable for the PE patients was not available at the time of filing.

In the studies described at pp. 33-41 of the present application, the protocol for administration of medication (either dapoxetine or placebo) was 1-3 hours prior to planned intercourse. Given the nature of the invention and the need for administration of an effective treatment close in time to anticipated intercourse, the ability to administer dapoxetine in the time range in claims 41, 42 and 52-54 is not merely optimization or discovery of workable ranges as asserted by the Examiner. Rather, such time parameters of administration claimed in the method of the present invention are an important part of the claimed invention. The prior art generally relating to SSRI's teaches the chronic administration of SSRI's for their primary therapeutic indication, depression and the expectation of the side effects associated with these drugs administered chronically. Moreover, the prior art considering the use of SSRI's for treating sexual dysfunction and in particular, PE had, prior to the present invention, not found effective on-demand therapy.

Thus, the aspect of therapeutically effective administration within three hours prior to intended sexual activity is unexpected and the prior art teaches away from it. Claims 41, 42 and 52-54 are therefore non-obvious in view of the cited prior art.

Respectfully submitted,

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Date: February 28, 2007

(viii) Claims Appendix.

Claim 37 (previously presented): A method of treating or managing sexual dysfunction in a mammal in need of treatment which comprises administering on an as-needed basis to the mammal a therapeutically effective amount of dapoxetine or a pharmaceutically acceptable salt thereof, wherein the sexual dysfunction is premature ejaculation, wherein the mammal is a human male, and wherein said administration of dapoxetine is effective for treating or managing premature ejaculation in the absence of priming doses.

Claim 38 (original): The method of claim 37, wherein dapoxetine is administered immediately prior to, to about 12 hours prior to a sexual activity.

Claim 39 (original): The method of claim 37, wherein dapoxetine is administered immediately prior to, to about 8 hours prior to a sexual activity.

Claim 40 (previously presented): A method of treating or managing sexual dysfunction in a mammal in need of treatment which comprises administering on an as-needed basis to the mammal a therapeutically effective amount of dapoxetine or a pharmaceutically acceptable salt thereof, wherein the sexual dysfunction is premature ejaculation, wherein the mammal is a human male, wherein dapoxetine is administered immediately prior to, to about 4 hours prior to a sexual activity and wherein said administration of dapoxetine is effective for treating or managing premature ejaculation in the absence of priming doses.

Claim 41 (original): The method of claim 37, wherein dapoxetine is administered immediately prior to, to about 3 hours prior to a sexual activity.

Claim 42 (original): The method of claim 37, wherein dapoxetine is administered immediately prior to a sexual activity.

Claim 51 (previously presented): A method of treating premature ejaculation in a human male which comprises administering orally to the human male about 0.01 mg to about 200 mg of dapoxetine or a pharmaceutically acceptable salt thereof immediately prior to, to about 4 hours prior to a sexual activity, wherein said administration of dapoxetine is effective for treating premature ejaculation in the absence of priming doses.

Claim 52 (previously presented): A method of treating premature ejaculation in a

human male which comprises administering orally to the human male about 0.01 mg to about 200 mg of dapoxetine or a pharmaceutically acceptable salt thereof immediately prior to, to about 3 hours prior to a sexual activity, wherein said administration of dapoxetine is effective for treating premature ejaculation in the absence of priming doses.

Claim 53 (previously presented): A method of treating premature ejaculation in a human male which comprises administering orally to the human male about 0.01 mg to about 200 mg of dapoxetine or a pharmaceutically acceptable salt thereof about 30 minutes to about 3 hours prior to a sexual activity, wherein said administration of dapoxetine is effective for treating premature ejaculation in the absence of priming doses.

Claim 54 (previously presented): A method of treating premature ejaculation in a human male which comprises administering orally to the human male about 0.01 mg to about 200 mg of dapoxetine or a pharmaceutically acceptable salt thereof immediately prior to a sexual activity, wherein said administration of dapoxetine is effective for treating premature ejaculation in the absence of priming doses.

(ix) Evidence Appendix.

Declaration of David A. Rivas, MD, submitted July 27, 2006 and entered by the Examiner in the Office Action dated October 3, 2006 at page 2.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	:	10/049,427	Confirmation No. 1087
Applicant	:	Thor	
Filed	:	6 May 2002	
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Examiner	:	Yong Soo Chong	
Docket No.	:	4220-78-PUS	
Customer No.	:	22442	

Declaration of David A. Rivas, MD
37 CFR 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313

Dear Sir:

I, David A. Rivas, declare as follows:

My curriculum vitae is attached. My employment and educational history is summarized below.

Johnson & Johnson Pharmaceutical Research and Development, Senior Director, Clinical Leader [Reproductive Health/Urology] August 2004-present

GlaxoSmithKline, Director, Discovery Medicine [Urogenital], Cardiovascular & Urogenital Center for Excellence and Drug Discovery November 2003-August 2004

Pfizer, Inc., Director, Global Clinical Research [Urology] April 2003-October 2003

Pharmacia Corporation, Director, Global Clinical Research [Urology]
Associate Director, Global Clinical Research [Urology] Nov. 2000-Dec. 2002

Various Faculty Appointments, 1994-2000

Various Post Graduate Positions, 1984-1994

M.D., Jefferson Medical College of Thomas Jefferson University
Philadelphia, Pennsylvania, 1980-1984

A.B., Distinction in All Subjects, Cornell University
Ithaca, New York, 1977-1980

1. I have reviewed U.S. Patent Application 10/049,427, the Office Action dated 10/4/2005 and the references cited therein, including the McMahon et al. article cited by the Examiner in the 10/4/05 Office action (McMahon et al., J Urology, v. 161, pp. 1826-30 (1999). Treatment of Premature Ejaculation with Paroxetine Hydrochloride as Needed: 2 Single-Blind Placebo Controlled Crossover Studies).

2. McMahon et al. is a pilot study exploring the merits of paroxetine (an SSRI specifically designed to treat conditions pertaining to mood and affect and which must be administered daily to achieve and maintain the desired therapeutic effect) in the treatment of men suffering with premature ejaculation (PE). The authors study objective is 'to determine whether paroxetine as needed 3-4 hours before sexual intercourse was more efficacious than placebo in the treatment of PE.'

3. McMahon et al. does not provide sufficient information to determine whether the week 1 treatment data of Study 1 are statistically significantly different from the control data. Since McMahon et al. does not state that the week 1 treatment data of Study 1 are statistically significantly different from the control data, I would assume that they are not. Consequently, I would not rely on the week 1 data as demonstrating an increase in ejaculatory latency.

   a. In relation to Study 1, the authors state that "[t]he ejaculatory latency time for groups A and B during treatment with paroxetine as needed was statistically superior to placebo at 2, 3, and 4 weeks ($p<0.001$, table 2, fig. 1)." This statement conveys to me, as one skilled in the art, that the authors do not consider the results at week 1, shown in table 2 and figure 1, to be statistically significant. Based on the authors' characterization of this data, it would be inappropriate for one to conclude that the week 1 data in Study 1 are statistically significant.

   b. The McMahon et al. paper does not provide sufficient information (standard deviation, confidence intervals, median values and range values) to permit interpretation of the week 1 data, particularly because of the

limited sample size and because intravaginal ejaculatory latency times (IELT) tend to be variable and not normally distributed.

c. As one skilled in the art, after reviewing the McMahon et al. paper and understanding that the week 1 data in Study 1 are not statistically significant, it would be inappropriate for one to conclude that the week 1 data demonstrates a statistically significant increase over control data in ejaculatory latency time. Therefore, I would not rely on the week 1 data as demonstrating an increase in ejaculatory latency.

4. McMahon et al.'s conclusions regarding as needed dosing of paroxetine does not allow one skilled in the art to draw any conclusions about whether or not as needed use of paroxetine in the absence of priming doses is efficacious because the "as needed" use of paroxetine in McMahon et al. does not preclude priming doses.

a. As noted above, the study objective of McMahon et al. was 'to determine whether paroxetine as needed 3-4 hours before sexual intercourse was more efficacious than placebo in the treatment of premature ejaculation.'

b. McMahon et al.'s statement that initial daily treatment improves the as needed efficacy of paroxetine was based on a greater mean ejaculatory latency time in Study 2 (initial daily dosing) than in Study 1 (no initial daily dosing). (McMahon et al., p. 1829, col. 1, ll. 20-25);

c. Mean ejaculatory latency time for study Groups A-D is calculated using all data throughout the treatment phases (i.e., multiple instances of intercourse per week over 4 week treatment phases) when paroxetine had been used over a period of time;

d. Paroxetine use throughout a 4 week period, even in Study 1 without prior 2 week daily dosing, is not "in the absence of a priming dose";

e. The McMahon et al. study design did not impose a minimum time interval between intercourse episodes and therefore, paroxetine from one dose that was not cleared from the body could, in combination with a subsequent dose, result in an increase in paroxetine exposure in the patient greater than a single dose, thereby functioning as a priming dose;

f. Therefore, McMahon et al.'s statement that "paroxetine as needed is significantly better if patients are initially treated with the drug daily," which is based on mean ejaculatory latency time, is not relevant to whether paroxetine is effective in the absence of a priming dose because the "as needed" use of paroxetine in McMahon et al. was not designed to avoid a priming dose effect.

5. The present application on p. 19, ll. 20-25 describes as needed dosing in the absence of priming doses. The concept of a priming dose refers to a prior dose of a drug that has not been cleared from the body at the time of administration of a subsequent dose of the drug.

6. There are a number of scientific and methodological issues in McMahon et al. that makes one question the results and therefore, makes it difficult to draw meaningful conclusions from the study regarding the study objective or whether paroxetine can be therapeutically effective as needed in the absence of priming doses, a question that was not even contemplated by the study.

a. Primary/Secondary Premature Ejaculation. The patient characteristics in McMahon et al. (Table 1) indicate that the study included men with both primary and secondary PE. The paper, however, does not specify how the patients with primary and secondary PE were distributed between Groups A and B. It is unclear, therefore, whether an uneven distribution of primary or secondary PE patients between the Groups may have introduced some bias in the study.

b. Absence of Adverse Events. McMahon et al. state that there were no side effects reported by the patients taking paroxetine as needed in Study 1 (i.e., no headache, dizziness, somnolence, anorexia, anejaculation, gastrointestinal upset, reduced libido, erectile dysfunction, etc.). This would be unusual for any study and especially unusual for a study with a compound (paroxetine) with known side effects. This result draws into question the integrity of the data collection methods. Therefore, it is difficult to draw meaningful conclusions from the study.

c. Behavior Modification/Bias. There are two examples of potential bias in the McMahon et al. study: clinical investigator (physician) bias due to a lack of blinding of the investigator and patient bias based on stopwatch usage.

i. Blinding. Patients with PE can respond to factors other than pharmaceutical treatment, such as suggestions, even inadvertent, from a physician. The McMahon studies were single-blind studies (the patient is blinded to whether he is taking placebo or drug, but the clinician is not). Therefore, the physicians could have provided inadvertent suggestions to patients that they would or would not see an effect based on whether paroxetine or placebo was being administered, thereby influencing the reported results to show a stronger treatment effect. The McMahon et al. study, being a single blind, rather than a double blind study, calls the results of the study into question, making it difficult to make meaningful conclusions.

ii. Stopwatch Measurement. McMahon et al. did not report the directions for stopwatch measurement of ejaculatory latency time. The manner in which this time interval is measured (e.g., whether the stopwatch is held by the patient or his partner) can introduce bias into reported results, particularly in a single blind study. This factor also raises questions about the reported results making meaningful conclusions based on the study difficult to draw.

d. Pretreatment Values. McMahon et al. report pretreatment values of IELT based on a three week baseline period whereas the pretreatment values of coitus frequency were based on a three month pretreatment period, and the study measures of IELT and coitus frequency are based on one week values. These differences in measurements make meaningful conclusions based on the results difficult.

7. I hereby declare that all statements made herein of my own are true and that all statements made on information and belief are believed to be true; and

further that the statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the subject application or any patent issuing therefrom.

21 July 2006

Date

David A. Rivas, MD

CURRICULUM VITAE 15 September 2005

David A. Rivas, MD
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Mobile: 215-688-2007
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Pharmaceutical Industry Experience

Senior Director, Clinical Leader [Reproductive Health/Urology] August 2004-present
Johnson & Johnson Pharmaceutical Research and Deveopment
920 Route 202
Raritan, NJ 08869
Responsibilities
Clinical Development Program Team Leader

- Develop Ph II clinical trials of a compound in the treatment of overactive bladder
- Regulatory submissions/interactions regarding the lead compound
- Submission of electronic IND May 2005
- Development of Clinical Development Plan
- Management of study and clinical activity budgets
- Develop clinical program for alternate indications for the compound
- Development of clinical trial protocols
- Establish and manage budget of clinical trials
- Contribute to Compound Development Team, including clinical report
- Review of candidate compounds for In-Licensing/Due Diligence
- Develop Global Advisory Board and board meetings
- Consultant to early development efforts to develop candidate compounds

Project physician, dapoxetine

- Develop Ph I and III clinical trials of dapoxetine in the treatment of premature ejaculation
- Interactions with regulatory agencies
- Submission of electronic NDA Dec 2004
- Assist with development of Clinical Development Plan
- Management of clinical study budgets
- Develop clinical program for line extension indications for the dapoxetine
- Development of clinical trial protocols
- Initiate and manage clinical trials, including budget
- Monitor and conduct clinical trials
- Contribute to Clinical Development Team
- Participate with KOLs on dapoxetine advisory boards

Director, Discovery Medicine [Urogenital] November 2003-August 2004
Cardiovascular & Urogenital Center for Excellence and Drug Discovery
GlaxoSmithKline
709 Swedeland Road
King of Prussia, Pennsylvania 19406
Responsibilities
Clinical Matrix Team Leader

- Develop Ph II clinical trials of 4 compound for the treatment of overactive bladder and premature labor
- Regulatory submissions/interactions regarding the compounds
- Submission of IND June 2005
- Development of Clinical Development Plan
- Management of study and clinical activity budgets
- Develop clinical programs for the compounds
- Development of clinical trial protocols
- Establish and manage budget of clinical trials
- Contribute to Project Team, including clinical report
- Review of candidate compounds for In-Licensing/Due Diligence
- Develop Global Advisory Board and board meetings
- Consultant to preclinical development efforts to develop candidate compounds
- Develop strategy for urogenital discovery medicine

Director, Global Clinical Research [Urology] April 2003-October 2003
Pfizer, Inc., 100 Route 206 North, Peapack, New Jersey 07977
Director, Global Clinical Research [Urology] Jan 2003-April 2003
Associate Director, Global Clinical Research [Urology] Nov 2000-Dec 2002
Pharmacia Corporation, 100 Route 206 North, Peapack, New Jersey 07977
Responsibilities
Tolterodine Clinical Development Program Team Leader
Initiate, conduct, and report Phase I/II and III clinical trials of tolterodine for voiding dysfunction and incontinence, interactions with regulatory agencies regarding the investigation, registration, and safety of tolterodine

- Development and annual revision of Clinical Development Plan
- Management of budget for all clinical activities
- Develop clinical programs
- Development of clinical trial protocols
- Establish and manage budget of clinical trials
- Monitor and conduct clinical trials
- Compose final clinical trial study reports
- Contribute to Brand Development Team
- Clinical report to Project Development Team
- Review of candidate compounds for In-Licensing Lead Generation Team
- Participate with KOLs on Tolterodine Global and US advisory Boards
- Contribute to regulatory submissions
- Correspondance/Response to regulatory agency inquiries
- Preparation of annual regulatory clinical safety reports

Regulatory submissions
Tolterodine PR Mutual Recognition Procedure – Approval July 11, 2001
Japan NDA submission 26 February 2002
Pediatric sNDA submission 14 October 2003, 6 months exclusivity granted April 2004

Instructional Courses: Drug Development

CRO-Investigator Support Initiative	11/29-12/1/00
PERI Global Clinical Trials	2/21-3/01
PERI Drug Development I	2/5-7/01
PERI Drug Development II	6/11-13/01
DIA Statistics	3/26-7/01
EAGLE Initiative I	3/29-31/01
Franklin-Covey Leadership	5/14-15/01
Decker Speaker Training	5/16/01
Medical Writing I	7/25-6/01
Franklin-Covey WMM	7/23/01
EAGLE Initiative II	8/30-1/01
Success with CROs Training Course	9/24-5/01
Barnett Pediatric Clinical Trials	12/5-7/01
DIA Contemporary Pharmacovigilance and Risk Management	1/14-17/02
DIA Regulatory II: Marketing Application and Post-Approval Phase	2/18-20/02
DIA Japan: Pharmaceutical Development, Registration, and Culture	2/24-5/02
PERI NDA Game: FDA/Industry Interaction in Drug Development	4/3-5/02
Frontline Manager Training	5/9-10/02
Project Leadership Training	8/12-13/02
PERI FDA/Industry Project Management	9/9-11/02
Managing Business Risk	10/23/02
DIA European Regulatory Affairs	11/11/02
Developing a Resilient Organization	12/10/02
DIA Navigating HIPAA Regulations	4/11/03
DIA Pharmacokinetic and Pharmacodynamic Application in the Drug Development Process	4/3-5/2004
PERI Basic Pharmacology Training Course	4/19-21/2004
AAPS/FDA Workshop on Pharmacokinetics and Pharmacodynamics of Drugs in Pregnancy and Lactation	5/3-4/2004
GSK Drug Development Simulation Training	7/27-30/2004
J&J Manager and the Law	9/9-10/2004
J&J On the Starting Blocks Clinical Trial Conduct	10/12-5/2005
J&J MedDRA training	12/16/2004
J&J Presentation Skills	6/8/2005
DIA IND and CTA/NDA Regulatory Affairs Training	8/1-4/2005

Education
M.D., Jefferson Medical College of Thomas Jefferson University
Philadelphia, Pennsylvania
1980-1984

A.B., Distinction in All Subjects, Cornell University
Ithaca, New York
1977-1980

Post Graduate
Fellowship: Neuro-Urology and Incontinence
Thomas Jefferson University Hospital
Philadelphia, Pennsylvania
1992-1994

Residency: Urology
Thomas Jefferson University Hospital
Philadelphia, Pennsylvania
1987-1991

Assistant Surgeon: Chestnut Hill Hospital
Philadelphia, Pennsylvania
1986-1987

Residency: Surgery
Cooper Hospital/University Medical Center
Camden, New Jersey
1985-1986

Internship: Surgery
Medical College of Pennsylvania
Philadelphia, Pennsylvania
1984-1985

Specialty Review in Urology:
Cook County Graduate School of Medicine
Chicago, Illinois
1991

Faculty Appointments
Assistant Professor of Urology
Department of Urology
Jefferson Medical College of Thomas Jefferson University
Philadelphia, Pennsylvania
1994-2000

Director, Division of Neuro-Urology
Department of Urology
Jefferson Medical College of Thomas Jefferson University
Philadelphia, Pennsylvania
1996-2000

Director, Urology Residency Program
Department of Urology
Jefferson Medical College of Thomas Jefferson University
Philadelphia, Pennsylvania
1995-2000

Director, Transurethral Microwave Thermotherapy Treatment Center
Department of Urology
Jefferson Medical College of Thomas Jefferson University
Philadelphia, Pennsylvania
1997-2000

Instructor of Urology
Department of Urology
Jefferson Medical College of Thomas Jefferson University
Philadelphia, Pennsylvania
1992-1994

Faculty, Incontinence Center
Thomas Jefferson University
Philadelphia, Pennsylvania
1992-2000

Attending Physician
Thomas Jefferson University Hospital
Philadelphia, Pennsylvania
1992-2000

Consulting Physician
Magee Rehabilitation Hospital
Philadelphia, Pennsylvania
1993-2000

Consulting Physician
Wills Eye Hospital
Philadelphia, Pennsylvania
1995-2000

Urology Practice
Tri-County Urologic Associates, PC
Pottstown, Pennsylvania
1991-1992

Medical Licensures
New Jersey #MA46969 issued 1985
Pennsylvania #MD034854E issued 1985
Oregon #19179 (inactive) issued 1995
Delaware #C10005641 issued 1999
Drug Enforcement Administration #BR0232506

Certifications
Recertification, American Board of Urology February 28, 2002

Instructor for Physician Certification
Transurethral Microwave Thermotherapy of the Prostate
EDAP/Technomed
Norcross, GA
1997

Fellow, American College of Surgeons
October 26, 1995

Advanced Laser Training Program in
The VersaPulse Select Urology Laser
Temple University Hospital
Philadelphia, Pennsylvania
November 11, 1994

Certification, American Board of Urology February 28, 1993

Operative Laparoscopy for the Urologist
Including Contact Nd:YAG Laser Therapy
Thomas Jefferson University Hospital
Philadelphia, Pennsylvania, 1991

Extracorporeal Shock Wave Lithotripsy
The Mid-Atlantic Kidney Stone Center
Marlton, New Jersey, 1989

Laser Education Program
Thomas Jefferson University
Philadelphia, Pennsylvania, 1989

National Board of Medical Examiners
Philadelphia, Pennsylvania
Diplomate #291267, granted 1985

Professional Societies
American Medical Association
Pennsylvania Medical Society
Montgomery County Medical Society
American Urological Association
Urological Association of Pennsylvania
International Continence Society
Society for Urodynamics and Female Urology
American College of Surgeons
Societe Internationale D'Urologie

Educational programs
Program Director
"Practical Urology for the Primary Care Physician"
Thomas Jefferson University, Philadelphia PA
November 11, 1993

Program Director
"Transurethral Microwave Thermotherapy of the Prostate Using the Prostatron"
Physician Training and Certification Courses
Thomas Jefferson University, Philadelphia PA
8/18/97, 9/22/97, 12/15/97, 2/9/98, 6/15/98

Invited Speaker
"Transurethral Microwave Thermotherapy: Prostasoft 2.0 and 2.5"
"Perioperative Challenges of the New Millenium"
Continuing Medical Education Course
Thomas Jefferson University, Philadelphia, PA
5/14/98

Program Director
"Transurethral Microwave Thermotherapy: Prostasoft 2.0 and 2.5"
Continuing Medical Education/Physician Certification Course
Stanford University, Stanford CA
7/16/99

Invited Speaker
"Sacral Nerve Root Stimulation for the Treatment of Urgency Incontinence" Continuing Medical Education Course
Thomas Jefferson University, Philadelphia, PA
7/15/99

Committees and Academic Services
Committee on Alumni and Public Affairs, Thomas Jefferson University, 1994-2000
Monthly medical student lectures, Jefferson Medical College, 1994-2000
Dean's Committee on Medical Ethics Education, 1996.
Committee on Graduate Medical Education, 1996-2000.
Judge-Resident Essay Prize Competition, Mid-Atlantic Section of the American Urological Association Annual Meeting, Hot Springs, VA, September 1997
Scientific Session Moderator, Mid-Atlantic Section of the American Urological Association Annual Meeting, Hot Springs, VA, September 1997
Committee on Continuing Medical Education 2000-present

National Courses/Conferences
Invited Speaker
"Skeletal muscle-assisted micturition and continence,"
Urology Instructional Course, "State of the Art in Neuro-Urology, Neurostimulation and Neuromodulation"
American Spinal Injury Association 22 nd Annual Meeting
Seattle, WA, April 23, 1996.

Faculty: "Urodynamics"
American Urological Association Postgraduate Course
American Urological Association Surgical Learning Center
Houston, TX, October 12-13, 1996

Faculty: American Urological Association Office of Education
"Bladder dysfunction in neurologic disease: diagnosis and management"
American Urological Association National Convention San Diego CA, June 1998

Faculty: "Advances in Drug Therapies and Drug Delivery Systems"
International Continence Society Instructional Course
International Continence Society Annual Convention
Denver, CO, August 23, 1999

Editorial Article Reviewer
Neurourology and Urodynamics
Journal of Urology
American Journal of Physiology

Grants

"Functional, histological, and Molecular Analysis of Vanilloid Effect on Lower Urinary Tract Dysfunction"
Nemours Foundation
Principal Investigator, 2000

"A Randomized, Parallel-Group, Double-Blind, Placebo-Controlled Study Comparing the Safety, Tolerance, and Efficacy of RTX (resiniferatoxin) Topical Solution in Patients with Detrusor Hyperreflexia"
Afferon Corporation
Principal Investigator, 2000

"A Phase III, Multicenter, Double-Blind, Randomized, Placebo-Controlled, Parallel Group Study of the Efficacy and safety of Controlled-Release Darifenacin Versus Tolterodine in the Treatment of Subjects with Overactive Bladder"
Pfizer, Inc
Principal Investigator, 2000

"Dose-response Study of SB 223412 Effect on Bladder Function in the Rat Model of Spinal Cord Injury"
SmithKline Beecham Pharmaceuticals
Principal Investigator, 2000

"Prospective Evaluation of the Urethral Drainage Stent (UDS) for Patients with Urinary Retention Secondary to Prostate Obstruction"
Microvasive, Boston Scientific Corporation
Co-investigator 1999 - 2000

"Sacral Nerve Stimulation for Chronic Voiding Dysfunction" Medtronic Grant MDT-103
Medtronic Neurological
Principal Investigator, 1998-9

"Post-approval Sacral Nerve Stimulation Study for the Treatment of Urinary Voiding Dysfunction " Medtronic Grant MDT-103
Medtronic Neurological
Principal Investigator, 1999-2000

"In-Vivo Whole-bladder Response to SB223412 and Capsaicin in the Rat Model of Spinal Cord Injury"
SmithKline Beecham Pharmaceuticals
Principal Investigator, 1998-9

"An Open-label Study to Evaluate Patient Acceptance and Safety of OROS Oxybutynin Chloride in Urge Urinary Incontinence"
Alza Corporation
Principal Investigator, 1998-9

"A Dose Escalating, Single-Blind, Placebo-Controlled Trial Evaluating the Safety, Tolerance, and Effects of Resiniferatoxin"
Afferon Corporation
Principal Investigator, 1997-1999

"Dose Escalation Study of Tolterodine in Patients with Urinary Incontinence"
Pharmacia & Upjohn
Principal Investigator, 1997-8

"Molecular Analysis of Neurogenic Lower Urinary Tract Dysfunction"
Nemours Foundation
Principal Investigator, 1997-2000

"Intravesical Capsaicin for Treatment of Hyperreflexic Bladder"
American Paraplegia Society
Co-Investigator, 1995-1996

"Molecular Analysis of Normal Bladder and Interstitial Cystitis"
Thomas Jefferson University Dean's Overage Research Program
Co-Investigator, 1995-1996

"Bladder Physiology and Functional Recovery after Experimental Spinal Cord Injury"
American Foundation for Urologic Disease
Principal Investigator, 1993-1995

"Comparison of Sphincter Prosthesis and Sphincterotomy"
National Center of Medical Rehabilitation Research at the National Institute of Child Health and Human Development
Co-Investigator, 1993-1996

"Multicenter Open Label Study of the Safety and Efficacy of Oral Lomefloxacin as a Prophylactic Agent in Transrectal Prostate Biopsy"
Searle Pharmaceuticals
Co-Investigator, 1992-1994

"Prospective Evaluation of Terazosin in Spinal Cord Injured Men"
Abbott Pharmaceutical
Co-Investigator, 1992-1994

Honors and Awards

1. 26th Annual Meeting of the American Spinal Injury Association
   2000 Accorda Therapeutics 1st prize winner "Intravesical resiniferatoxin (RTX) treatment of detrusor hyperreflexia: results of a randomized single-blind, placebo-controlled multicenter trial"

2. 2000 Philadelphia Urological Society 2nd place Basic Science Category Resident Essay "Methylprednisolone and mianserin improve recovery of bladder function after spinal cord injury in the rat model"

3. 1999 Philadelphia Urological Society 1st place Basic Science Category Resident Essay "Molecular analysis of bladder smooth muscle actin isomers in a rat model of spinal cord injury."

4. 24th Annual Meeting of the American Spinal Injury Association
   1998 Accorda Therapeutics 1st prize winner
   "Bladder smooth muscle isoactin gene expression in the rat model of spinal cord injury"

5. 1997-8 AUA/Circon ACMI Prize Essay Contest, Co-author
   Third Place, Clinical Research Category
   "Sphincter stent versus external sphincterotomy in spinal cord injured men; prospective randomized multicenter trial"

6. 23rd Annual Meeting of the American Spinal Injury Association
   1997 Poster Competition, First Place Award
   "Electrically stimulated skeletal muscle urinary neosphincter for stress urinary incontinence"

7. 22 nd Annual Meeting of the American Spinal Injury Association
   1996 Poster Competition Second Place Award
   "Gracilis urethromyoplasty-the creation of a new autologous urinary sphincter in neurologically impaired patients"

8. 1995 Mid-Atlantic Section of the American Urological Association
   Basic Science Essay-2nd place prize
   "Gracilis muscle dynamic urethral sphincter myoplasty: rat model experience"

9. 1995 Philadelphia Urological Association
   Annual Resident Essay Contest, First Prize, Clinical Research
   "Management of sphincter dyssynergia in SCI men with indwelling catheter using the sphincter stent prosthesis"

10. 21rd Annual Meeting of the American Spinal Injury Association
    1995 Poster Competition, First Place Award
    "Gracilis muscle dynamic urethral sphincter myoplaty: rat model experience"

11. 1994 Philadelphia Urological Association Annual Resident Essay Contest
    Third Prize, Clinical Research
    "Latex allergy in spinal cord injury"

12. 20th Annual Meeting of the American Spinal Injury Association
1994 Poster Competition, First Place Award
"Three year follow-up of the urinary sphincter stent for the treatment of sphincter dyssynergia in spinal cord injury patients"

13. 20th Annual Meeting of the American Spinal Injury Association
1994 Poster Competition, First Place Award
"Complications of vacuum constriction device for treatment of erectile dysfunction in spinal cord injury men"

14. 20 th Annual Meeting of the American Spinal Injury Association
1994 Poster Competition Second Place Award "Detrusor-myoplasty: skeletal muscle wrap of the urinary bladder; animal and clinical experience"

15. 1993 American Urological Association
Jack Lapides Essay Contest on Neuro-Urology/Urodynamics, Grand Prize,
Co-Author "Evaluation of skeletal muscle wrap of the urinary bladder and functional neuromuscular electrical stimulation: detrusor myoplasty"

16. 1993 Philadelphia Urological Association
Annual Resident Essay Contest, Second Prize, Basic Research
"Micturition patterns in rat model spinal cord injury"

17. 1993 World Congress on Endourology
Essay Contest, 1st Prize
"Prospective evaluation of external sphincter prosthesis placement with external sphincterotomy in spinal cord injured men"

18. 1993-95 American Foundation for Urologic Disease
Research Scholar
"Bladder physiology and functional recovery following experimental spinal cord trauma"

Electronic Education

1. Chancellor, M.B., Rivas, D.A.: Urinary Incontinence. Williams & Wilkins' World Wide Web Medical School Education. 1996.

2. Rivas, D.A., Chancellor, M.B.: Benign Prostatic Hyperplasia. Williams & Wilkins' World Wide Web Medical School Education. 1996.

Publications

1. Bagley, DH and Rivas, DA: Upper urinary tract filling defects: flexible ureteroscopic diagnosis. J Urol 143: 1196, 1990.

2. Chancellor, MB, Rivas, DA, Erhard, MJ, Hirsch, IH, Bagley, DH: Flexible cystoscopy during urodynamics of spinal cord injured patients. J Endourology, 7(6); 531-535, 1993.

3. Rivas, DA, Chancellor, MB, Hill, K, Friedman, M: Neurologic manifestations of baclofen withdrawal. J Urol 150: 1903-1905, 1993.

4. Chancellor, MB and Rivas, DA: The American Urological Association symptom index for women with voiding symptoms; lack of specificity for benign prostatic hyperplasia. J Urol 150: 1706-1709, 1993.

5. Chancellor MB, Erhard MJ, Rivas DA: Clinical effect of alpha-1 antagonist terazosin on external and internal urinary sphincter. J American Paraplegia Society, 16:207-214, 1993.

6. Abdill, CK, Rivas, DA, Chancellor, MB: Transurethral placement of external sphincter wire mesh stent for neurogenic bladder. American Association Spinal Cord Injury Nurses 11(2):38-41, 1994.

7. Chancellor, MB, Rivas, DA, Huang, B, Kelly, G, Salzman, SK: Micturition patterns after spinal trauma as a measure of autonomic functional recovery. J Urol 151: 250-254, 1994.

8. Chancellor, MB, Erhard, MJ, Kiilholma, PJ, Rivas, DA: Functional urethral closure with pubovaginal sling for destroyed female urethra after long-term urethral catheterization. Urology 43(4): 499-505, 1994.

9. Chancellor, MB, Rivas, DA, Abdill, CA, Karasick, S, Ehrlich, SM, Staas, WE: Prospective comparison of external sphincter balloon dilitation and prosthesis placement with external sphincterotomy in spinal cord injured men. Arch Physical Med Rehab 75: 297-305, 1993.

10. Chancellor MB, Rivas DA, Liberman SN, Moore J, Staas, WE: Cystoscopic autogenous fat injection for the treatment of vesicoureteral reflux in spinal cord injury. J American Paraplegia Society, 17(4):50-54, 1994.

11. Chancellor MB, Rivas DA, Panzer DE, Friedman M, Staas WE: Prospective comparison of topical minoxidil to vacuum constriction device and intracoporal papaverine injection in the treatment of erectile dysfunction due to spinal cord injury. Urology, 43(3): 365-369, 1994.

12. Chancellor MB, Rivas DA, Salzman SK: Detrusor-myoplasty to restore micturition. Lancet 343:669, 1994.

13. Rivas, DA, Chancellor MB: Complications associated with the use of vacuum constriction devices for erectile dysfunction in the spinal cord injured population. J Am Paraplegia Soc 17:137-140, 1994.

14. Rivas, DA and Chancellor, MB: Prospective comparison of external sphincter prosthesis placement with external sphincterotomy in spinal cord injured men. J Endourol 8:89-93, 1994.

15. Rivas, DA and Chancellor, MB: Flexible cystoscopy in spinal cord injury. Paraplegia 32: 454-462, 1994.

16. Chancellor MB, Rivas DA, Ackman D, Appell RA, Binard J, Boon TB, Roehrborn CG, Chetner MP, Thorndike WC, Defalco A, Mayo M, Gajewski J, Green B, Bennett J, Foote J, Juma S, Linsenmeyer T, McMillan R, Stone A, Vasquez A: Multicenter trials of Urolume^{TM} Endourethral Wallstent^{R} prosthesis for the urinary sphincter in spinal cord injured men. J Urol 152: 924-930, 1994.

17. Chancellor MB, Rivas DA, Keeley FX, Lofti MA, Gomella LG: Similarity of the American Urological Association Symptom Index among men with benign prostatic hyperplasia (BPH), urethral obstruction not due to BPH, and detrusor hyperreflexia without outlet obstruction. Brit J Urol, 74: 200-203, 1994.

18. Rivas, DA and Chancellor, MB: Utility of the American Urological Association symptom index in the diagnosis and treatment of women with voiding dysfunction. Int Urogyn J 5(4): 202-207, 1994.

19. Chancellor, MB, Rivas, DA, and Staas, WE: DDAVP in the urological management of the difficult neurogenic bladder in spinal cord injury: Preliminary report. J Amer Paraplegia Soc 17:165-167, 1994.

20. Shenot, P, Rivas, DA, Kalman, DD, Staas WE, Chancellor, MB: Latex allergy manifested in Urological surgery and care of spinal cord injured patients. Arch Phys Med Rehabilitation 75:1263-5, 1994.

21. Chancellor MB, Acosta R, Rivas DA, Erhard MJ, Moore J, Salzman SK: Detrusor myoplasty and functional neuromuscular electrical stimulation of the urinary bladder after experimental spinal trauma. Neurourology and Urodynamics 13: 547-558, 1994.

22. Chancellor MB, Liu JB, Rivas DA, Karasick S, Alexander A, Martin DM, Bagley DH, Goldberg B: Intraoperative endoluminal ultrasound evaluation of urethral diverticulum. J Urol 153: 72-75, 1994.

23. Gomella LG, Lotfi MA, Rivas DA, Chancellor MB: Contact laser vaporization techniques for benign prostatic hyperplasia. J Endourology 9(2): 117-122, 1995.

24. Rivas, DA, Chancellor, MB, Huang, B, Salzman, SK: Autonomic dysreflexia in a rat model of spinal cord injury and the effect of pharmacologic agents. Neurourology and Urodynamics 14(2): 141-152, 1995.

25. Chancellor MB, Rivas DA, Abdill CK, Staas WE, Bennett CJ, Finocchiaro MV, Razi S, Bennett JK, Green BG, Foote JE, Killorian RW: Management of sphincter dyssynergia using the sphincter stent prosthesis in chronically catheterized SCI men. J Spinal Cord Med 18: 88-94, 1995.

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Presentations

1. Functional urethral closure with pubovaginal sling for the destroyed female urethra after long-term urethral catheterization. Joint meeting of the American Urogynecology Society and Urodynamic Society, San Antonio, TX, November, 1993.

2. Prospective evaluation of external sphincter prosthesis placement with external sphincterotomy in spinal cord injured men. Presented as Essay Contest 1st Prize Winner to the World Congress on Endourology, Florence, Italy, October, 1993.

3. Complications associated with the use of vacuum constriction devices for erectile dysfunction in the spinal cord injured population. Annual Convention of the American Paraplegia Society, Las Vegas, NV, September, 1993.

4. Autonomic dysreflexia in a rat model of spinal cord injury: effect of pharmacologic agents. Urodynamics Society, American Urological Association Annual Convention, San Antonio, TX, May, 1993.

5. Comparison of erectile response to intraurethral, topical, and intracorporal application of vasoactive substances in the rat model of spinal cord injury. American Spinal Injury Association Annual Convention, Philadelphia, PA, April, 1994.

6. Comparison of the American Urological Association symptom index between women and men. American Urological Association Annual Convention, San Francisco, California, May, 1994.

7. Comparison of erectile response to intraurethral, topical, and intracorporal pharmacotherapy in the rat model of spinal cord injury. American Urological Association Annual Convention, San Francisco, California, May, 1994.

8. DDAVP in the symptomatic management of voiding symptoms in men with benign prostatic hyperplasia. American Urological Association Annual Convention, San Francisco, California, May, 1994.

9. Endoluminal ultrasound evaluation of urethral diverticula and periurethral mass. American Urological Association Annual Convention, San Francisco, California, May, 1994.

10. Comparison of erectile response to intraurethral, topical, and intracorporal pharmacotherapy in the rat model of spinal cord injury.
American Paraplegia Society Annual Convention, Las Vegas, NV, September, 1994.

11. Long-term follow-up of sphincter stent prosthesis in spinal cord injury.
American Paraplegia Society Annual Convention, Las Vegas, NV, September, 1994.

12. Comparison of erectile response to topical and intraurethral application of minoxidil in the rat model of spinal cord injury to that of the clinical response to topical minoxidil in SCI men. Mid-Atlantic Section of the American Urological Association Annual Meeting, Philadelphia, PA, September 23, 1994.

13. A molecular marker for the development of interstitial cystitis in a rat model: isoactin gene expression. NIDDK 1995 Interstitial Cystitis Scientific Research Symposium, National Institutes of Health, Bethesda, MD, January 9, 1995.

14. The effect of myomyotomy on bladder rupture in a rat model of bladder augmentation. Urodynamics Society, American Urological Association Annual Convention, Las Vegas, NV, April 23, 1995.

15. Contact Nd:YAG laser ablation of the external urinary sphincter in spinal cord injured men with detrusor-sphincter dyssynergia. American Urological Association Annual Convention, Las Vegas, NV, April 25, 1995.

16. Isoactin gene expression in the rat model of spinal cord injury; a potential early marker of long-term bladder function and risks. American Urological Association Annual Convention, Las Vegas, NV, April 24, 1995.

17. Epidemiology of current treatment for sexual dysfunction in spinal cord injured men in the model spinal cord injury centers. American Spinal Injury Association Annual Convention, Orlando FL, May 1995.

18. Bladder smooth muscle gene expression in spinal cord injury; potential early marker of long-term bladder function and risks. American Spinal Injury Association Annual Convention, Orlando FL, May 1995.

19. Gracilis muscle dynamic urethral sphincter myoplasty: rat model experience. American Spinal Injury Association Annual Convention, Orlando FL, May 1995.

20. A molecular marker for the development of interstitial cystitis in a rat model: Isoactin gene expression. Mid-Atlantic Section of the American Urological Association Annual Meeting, Southampton, Bermuda, September 19, 1995.

21. Bladder smooth muscle isoactin gene expression in the rat model of spinal cord injury. American Urological Association Annual Convention, Orlando, FL May 1996.

22. Bladder smooth muscle isoactin gene expression in the rat model of spinal cord injury. American Spinal Injury Association Annual Convention, Seattle, WA April 1996.

23. Effect of urinary tract reconstruction in neurologically impaired women. American Spinal Injury Association Annual Convention, Seattle, WA April 1996.

24. Gracilis urethromyoplasty- the creation of a new autologous urinary sphincter in neurologically impaired patients. American Spinal Injury Associationn Annual Convention, Seattle, WA April 1996.

25. Electrically stimulated skeletal muscle urinary neosphincter for stress urinary incontinence. American Spinal Injury Association Annual Convention, Houston, TX March 1997.

26. Intravesical capsaicin for neurogenic bladder dysfunction. American Spinal Injury Association Annual Convention, Houston, TX March 1997.

27. Continuous vs. conventional urodynamic studies in spinal cord injured patients. American Spinal Injury Association Annual Convention, Houston, TX March 1997.

28. Rivas DA, Chancellor MB, Watanabe T, Shenot PJ, Figueroa TE: Methylprednisolone and mianserin improve recovery of bladder function after spinal cord inury in the rat model. American Spinal Injury Association Annual Convention, Houston, TX March 1997.

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32. Rivas DA, Hong R, Watanabe T, Crewalk J, Quinn D, Bourgeois I, Chancellor MB: An autologous skeletal muscle urinary neosphincter (gracilis urethromyoplasty) for the treatment of incontinence in neurologically impaired patients. American Urological Association Annual Convention, New Orleans, LA April 1997.

33. Rivas DA, Watanabe T, Shenot PJ, Figueroa TE, Chancellor MB. Methylprednisolone and mianserin improve recovery of bladder function after spinal cord injury in the rat model. American Paraplegia Society Annual Convention. Las Vegas, NV Sept 1997.

34. Rivas DA, Shenot PJ, Shupp-Byrne D, McCue P, Sedor J, Chancellor MB, deGroat WC, Fraser MO, Jordan ML. Effects of ethanol and oil vehicles for intravesical capsaicin treatment. American Spinal Injury Association Annual Convention, Cleveland OH March 1998.

35. Rivas DA, Shenot PJ, Figueroa TE, McHugh K, Shupp-Byrne D, Huang B, Chancellor MB. Bladder smooth muscle isoactin gene expression in the rat model of spinal cord injury. American Spinal Injury Association Annual Convention, Cleveland OH March 1998.

36. Rivas, D.A., Shenot, P.J., Stuligowa, K., Quinn, D., Green, B., Fraser, M., Kim, D., Lavelle, J., Erickson, J. deGroat, W.C., and Chancellor, M.B.: Intravesical resinaferatoxin (RTX) treatment of detrusor hyperreflexia: Results of a randomized double-blind, placebo-controlled trial. American Urological Association Annual Convention Dallas, TX, May 1999.

37. Rivas, D.A., Shenot, P.J., Stuligowa, K., Quinn, D., Green, B., Fraser, M., Kim, D., Lavelle, J., Erickson, J. deGroat, W.C., and Chancellor, M.B.: Intravesical resinaferatoxin (RTX) treatment of detrusor hyperreflexia: Results of a randomized double-blind, placebo-controlled trial. Society for Female Urology and Urodynamics, American Urological Association Annual Convention, Dallas, TX, May 1999.

38. Rivas, DA: The vanilloids: capsaicin and resiniferatoxin: novel therapy for the treatment of detrusor hyperreflexia. International Continence Society Annual Convention, Denver, CO Agust 23, 1999.

39. Rivas DA, Shenot PJ, Green B, Frazer MO, deGroat WC, Chancellor MB: Intravesical resiniferatoxin (RTX) treatment of detrusor hyperreflexia: results of a randomized, placebo-controlled, multicenter trial. American Paraplegia Society Annual Convention, Las Vegas NV, September 1999

40. Rivas, DA, Chancellor, MB, Green, B, Quinn D, Shenot, PJ: Intravesical resinaferatoxin (RTX) treatment of detrusor hyperreflexia: Results of a randomized double-blind, placebo-controlled trial. Mid-Atlantic Section of American Urological Association Annual Convention, Hilton Head, SC, October 1999.

41. Rivas DA, Figueroa TE, Hay D, Oh J, Shenot PJ. Evidence for a role of tachykinins in detrusor hyperreflexia: a study of NK3 antagonists in the rat model of spinal cord injury. American Spinal Injury Association Annual Convention, Chicago, IL April 14, 2000.

42. Rivas DA, Shenot PJ, Vasavada SP, Quinn D, Hubert C, Chancellor MB, deGroat WC, Kim DY, Erikson J, Green B, Kennelly M. Intravesical resiniferatoxin (RTX) increases bladder capacity and improves continence in patients with refractory detrusor hyperreflexia: a randomized, blinded, placebo-controlled trial. Society for Urodynamics and Female Urology, American Urological Association Annual Convention, Atlanta, GA April 29,2000.

43. Rivas DA, Schmidt RA, van Kerrebroeck PEV, Janknegt RA, Lycklama a Nijolt AAB, Hassouna MH, Siegel SW, Jonas U, Fowler CJ. Interstim therapy: proper placement in the treatment ladder. American Urological Association Annual Convention, Atlanta, GA May 2,2000.

44. Rivas DA, Shenot PJ, Vasavada SP, Quinn D, Hubert C, Chancellor MB, deGroat WC, Kim DY, Erikson J, Green B, Kennelly M. Intravesical resiniferatoxin (RTX) increases bladder capacity and improves continence in patients with refractory detrusor hyperreflexia: a randomized, blinded, placebo-controlled trial, American Urological Association Annual Convention, Atlanta, GA May 2, 2000.

45. Rivas DA, Figueroa TE, Hay D, Shenot PJ. Evidence for a role of tachykinins in detrusor hyperreflexia: a study of NK3 antagonists in the rat model of spinal cord injury. American Urological Association Annual Convention, Atlanta, GA May 2, 2000.

46. Rivas DA, Shenot PJ. Holmium:YAG laser lithotripsy of bladder calculi in spinal cord injured patients. American Paraplegia Society Annual Conference, Las Vegas, NV Septenber 5, 2000.

47. Rivas DA, Chancellor MB, Sathyan G, Gupta S. Effect on Salivary output following controlled-release oxybutynin and tolterodine. Mid-Atlantic Section of American Urological Association Annual Convention, Rio Grand, PR October 15, 2001.

48. Rivas DA, Gomella LG, Hirsch IH, Strup SE, Shenot PJ, Casale P, Mulholland SG. Transurethral microwave thermotherapy (TUMT) of the prostate without IV sedation: Results of a single US center using both low-energy and high-energy protocols. Mid-Atlantic Section of American Urological Association Annual Convention, Rio Grand, PR October 18, 2001.

49. Rivas DA. Urethral suspension surgery as treatment for post-prostatectomy incontinnce: the new millennnium sling. Invited speaker, Mid-Atlantic Section of American Urological Association Annual Convention, Rio Grand, PR October 18, 2001.

Accepted Abstracts

1. Erhard, MJ, Chancellor, MB, Rivas, DA, Kiilholma, P: Pubovaginal sling for the treatment of destroyed female urethra secondary to long-term foley catheter drainage. American Spinal Injury Association Annual Convention, May 10-12, 1993, San Diego, CA.

2. Chancellor, MB, Rivas, DA, Huang, B, Hirsch, IH, Filmer, RB, Salzman, SK: Micturition patterns after experimental rat model spinal cord injury. American Spinal Injury Association Annual Convention, May 10-12, 1993, San Diego, CA.

3. Chancellor, MB, Liberman, S, Rivas, DA, Moore, J: Autogenous fat injection in the treatment of vesicoureteral reflux in spinal cord injury: preliminary report. American Spinal Injury Association Annual Convention, May 10-12, 1993, San Diego, CA.

4. Erhard, MJ, Chancellor, MB, Rivas, DA, Staas, WE: Evaluation of terazosin for the treatment of voiding dysfunction in spinal cord injury. American Spinal Injury Association Annual Convention, May 10-12, 1993, San Diego, CA.

5. Rivas, DA, Chancellor, MB, Huang, B, Salzman, SK: Autonomic dysreflexia in a rat model spinal cord injury and the effect of pharmacologic agents. Urodynamics Society, American Urological Association Annual Convention, May 15, 1993, San Antonio TX.

6. Huang, B, Rivas, DA, Chancellor, MB: Autonomic dysreflexia in a rat model of spinal cord injury and the effect of pharmacologic agents. American Paraplegia Society Annual Convention, Las Vegas, NV, September 1993. JAPS 16:276, 1993

7. Rivas, DA, Moore, J, Chancellor, MB: Complications of vacuum constriction devices for the treatment of erectile dysfunction in spinal cord injury men. . American Paraplegia Society Annual Convention, Las Vegas, NV, September 1993. JAPS 16:250, 1993

8. Chancellor, MB, Rivas, DA, Acosta, R, Erhard, MJ, Salzman, SK: Detrusor myoplasty: Skeletal muscle wrap of the urinary bladder and functional neuromuscular electrical stimulation. . American Paraplegia Society Annual Convention, Las Vegas, Nevada, September 1993. JAPS 16:273, 1993

9. Abdill, CK, Rivas, DA, Chancellor, MB, : Urodynamic evaluation of spinal cord injured patients using flexible cystoscopy. American Association of Spinal Cord Injury Nurses 1993.

10. Chancellor, MB, Rivas, DA, Karasick, S, Liu, J, Alexander, DA, Merton, DA, Goldberg, BB: Endoluminal ultrasound evaluation of urethral diverticulum and periurethral mass. American Uro-Gynecology Society, San Antonio, TX October 1993.

11. Chancellor, MB, Rivas, DA, Kiilholma, PJ: The application of the new American Urological Association symptom index for women with voiding symptoms. American Uro-Gynecology Society, San Antonio, TX October 1993.

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13. Hirsch IH, Chancellor MB, Rivas DA, Sedor J, Shupp-Byrne D: Male reproductive rehabilitation: adjunctive diagnostic and therapeutic techniques. American Society of Andrology Annual Convention, Springfield, IL March 1994.

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(x) Related Proceedings Appendix.

None.